

REMARKS

Reconsideration and withdrawal of the requirement for restriction are requested.

Claims 1-161 are pending in this application. No new claims are added. Claims immediately subsequent to claims 24 and 25, which were unintentionally misidentified in the originally-filed application using the duplicative claim numbering as “claim 24” and “claim 25,” have been renumbered as claim 34 and claim 161, respectively.

Claims 12, 13, 16-18, 35, 36, 41-43, 67, 68, 76, 77, and 108 have been amended to be in compliance with the requirements set forth for multiple dependent claims pursuant to 37 C.F.R. 1.75(c) and M.P.E.P. 608.01(n). Claims 106 and 150 have been amended to correct unintentional typographical errors.

No new matter is added.

The claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§101, 102, 103 or 112. Rather, these additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

The Office Action required an election under 35 U.S.C. §121 from among the following groups:

Group I: Claims 1-8, 123 and 124 drawn to a diagnostic kit comprising WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus;

Group II: Claims 9, 14 and 15 drawn to a method of detecting WNV infection in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure;

Group III: Claims 10, 14, 15, 19-23, 26-33, 37-40, 44-59, 61-66, 125, drawn to a method of detecting a flavivirus infection in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure that is cross-reactive with antibodies against flavivirus other than MNV;

Group IV: Claims 11, 14 and 15 drawn to a method of detecting a protective immune response in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure;

Group V: Claim 60, drawn to a method for the transfer of information obtained as a result of carrying out any of the methods of claims 1, 9, 10, 11, 19, 32, 33, 44 or 53. Note that claim 1 is a product claim and therefore there can be no information as a result of carrying out that claim;

Group VI: Claims 69-73, drawn to a diagnostic kit comprising MNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against MNV and not reactive with antibodies against a flavivirus other than MNV;

Group VII: Claims 74, 78, 79, 80-105, 126-128 and 145 drawn to a method of detecting a MNV seropositivity in a subject utilizing a MNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against MNV and not reactive with antibodies against a flavivirus other than MNV;

Group VIII: Claims 75, 78, 79 and 105 drawn to a method of detecting a protective immune response in a subject utilizing a MNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against MNV and not reactive with antibodies against a flavivirus other than MNV;

Group IX: Claim 106 drawn to a method for discriminating an ongoing MNV infection from a seroconversion to a killed flavivirus vaccine via screening for both anti-E antibodies and anti-NS5 antibodies;

Group X: Claim 107 drawn to a method for detecting a recent or ongoing MNV infection via screening for both anti-E antibodies and anti-NS5 antibodies;

Group XI: Claims 129-136, 138-141, 146 and 147, drawn to a method of detecting antibody to a serospecific Dengue virus in a subject utilizing a serospecific DENV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against a flavivirus other than that particular DENV serotype;

Group XII: Claim 137, drawn to a diagnostic kit comprising a serospecific DENV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where

the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against other flaviviruses;

Group XIII: Claims 142 and 143, drawn to a method of determining whether a previously DENV-vaccinated animal recently sustained exposure to DENV using DENV NS5 protein having a native conformation or non-denatured structure where the NS5 protein is reactive with DENV antibodies and not reactive with antibodies against a flavivirus other than DENV;

Group XIV: Claims 144 and 148 drawn to a method of detecting a flavivirus infection in a subject using a microsphere is coupled to a flavivirus NS5 protein having a native conformation or non-denatured structure where each NS5 protein is reactive to said flavivirus but not cross-reactive to other flaviviruses;

Group XV: Claims 149-155 and 160 drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to flavivirus antigens;

Group XVI: Claim 156, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a MNV NS5 antigen with the amino acid sequence of SEQ ID NO. 8;

Group XVII: Claim 157 drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 10;

Group XVIII: Claim 158, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 12; and

Group XIX: Claim 159, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a MNV E glycoprotein antigen with the amino acid sequences of SEQ ID NO. 6.

Group VII, claims 74, 78, 79, 80-105, 126-128 and 145, is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications

to non-elected subject matter. It is requested that Groups VI (claims 69-73), VIII (claims 75, 78, 79 and 105), and XVI (claim 156) be searched and examined together in this application.

The claims of Group VII and those of Groups VI, VIII, and XVI are related because they are all drawn to methods and kits for utilizing WNV NS5 protein, or a fragment thereof, for detecting, with specificity, antibodies against WNV in a biological sample such that the WNV NS5 protein is not reactive with antibodies against other types of flaviviruses.

In this regard, the Examiner's attention is respectfully directed to MPEP § 808.02 which states, "... restriction is not required unless one of the following reasons appears:

- (1) Separate classification;
- (2) Separate status in the art; or
- (3) Different field of search . . ."

There is no evidence presented in the Office Action to demonstrate that the claims of the four Groups have acquired separate status in the art. Importantly, the claims in all four Groups involve the detection, with specificity, of antibodies against WNV by way of kits or methods that involve WNV NS5 protein, or fragment thereof, which is reactive with antibodies against WNV but not reactive with antibodies against a flavivirus other than WNV. In other words, the WNV NS5 protein, or fragment thereof, is specific for detecting the presence of antibodies against WNV in biological samples. Thus, the claimed subject matter of Groups VI, VII, VIII, and XVI each overlap under one, unified inventive concept.

Accordingly, it is respectfully submitted that the restriction is not appropriate.

Additionally, the Examiner's attention is respectfully further directed to the text of MPEP § 803 which in part states:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits ...

A search of the claims in Group VII will involve a search of Groups VI, VIII, and XVI, and should therefore be rejoined to elected Group VII.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite

showing of serious burden has not been made in the Office Action and there are relationships between the claims of Groups VII and with the claims of Groups VI, VIII, and XVI. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of all four Groups can be made without undue burden on the Examiner. All of the preceding, therefore, mitigates against restriction.

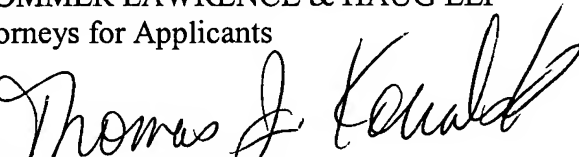
Although not an elected Group, the Examiner indicated that the technical feature linking groups I-V, IX, X, and XVIII "relate[s] to the use of WNV E protein, or fragment thereof, having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus." The Examiner contended that this technical feature "lacks novelty in the art" and cited Davis et al., J. Virol., May 2001, 75(9):4040-47. Applicants respectfully disagree. First, Group XVIII is not drawn to the use of WNV E protein but rather a method involving DENV NS5. In addition, Davis et al. does not anticipate or render obvious the present invention as the reference does not teach or suggest a WNV E protein having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against another flavivirus.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction are requested, and an early action on the merits earnestly solicited.

Respectfully submitted,

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